



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

James G. METZ *et al.*

Group Art Unit: 1638

Appln. No.: 08/657,749

Examiner: Russell KALLIS

Filed: May 30, 1996

Atty. Docket: 16518.025

Title: Nucleic Acid Sequences Encoding a  
Plant Cytoplasmic Protein Involved in  
Fatty Acyl-CoA Metabolism

**REQUEST FOR CORRECTED FILING RECEIPT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

***Attn: Office of Initial Patent Examination's Filing Receipt Corrections***

Dear Sir:

Attached is a copy of the official filing receipt issued by the United States Patent and Trademark Office (USPTO) in the above-referenced application for which issuance of a corrected filing receipt is respectfully requested.

**Please make the corrections to the "CONTINUING DATA AS CLAIMED BY APPLICANT" to read as follows:**

**THIS APPLN IS A CIP OF PCT/US94/13686 11/30/94**

**WHICH IS A CIP OF 08/265,047 06/23/94 PAT 5,679,881.**

In support for these corrections, Applicants submit herewith an Amendment and Response to Office Action mailed November 19, 2003, which Response contains an amendment

to the priority claim as it appears in the specification. Support for these amendments can be found in the transmittal filed with the application on May 30, 1996, and in the Declaration. A courtesy copy of the Declaration is attached.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any fees are required in the present application, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 16518.025.

Respectfully submitted,

A handwritten signature in cursive script that reads "Rachel L. Adams".

Rachel L. Adams (Reg. Attorney No. 54,660)  
David R. Marsh (Reg. Attorney No. 41,408)  
Holly Logue Prutz (Reg. Attorney No. 47,755)

Date: December 16, 2003

ARNOLD & PORTER  
555 Twelfth Street, N.W.  
Washington, D.C. 20004-1206  
(202) 942-5000 telephone  
(202) 942-5999 facsimile

FILING RECEIPT



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
08/657,749	05/30/96	1804	\$1,134.00	CGNE-101-2	59	28	4

CALGENE INC  
1920 FIFTH STREET  
DAVIS CA 95616



Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

JAMES G. METZ, DAVIS, CA; KATHRYN D. LARDIZABAL,  
WOODLAND, CA; MICHAEL W. LASSNER, DAVIS, CA.

CONTINUING DATA AS CLAIMED BY APPLICANT-

~~CIP THIS APPLN IS A 371 OF PCT/US94/13686 11/30/94~~  
~~WHICH IS AND A CIP OF 08/265,047 06/23/94 PAT 5,679,881~~  
~~WHICH IS A CIP OF 08/160,602 11/30/93 ABN~~  
~~WHICH IS A CIP OF 06/629,905 07/11/84 PAT 4,586,829~~  
~~WHICH IS A CIP OF PCT/US92/09863 11/13/92~~  
~~AND A CIP OF 07/933,411 08/21/92 ABN~~  
~~WHICH IS A CIP OF 07/796,256 11/20/91 ABN~~

FOREIGN FILING LICENSE GRANTED 11/15/96

TITLE

NUCLEIC ACID SEQUENCES ENCODING A PLANT CYTOPLASMIC PROTEIN INVOLVED  
IN FATTY ACYL-COA METABOLISM

PRELIMINARY CLASS: 435

COPY

CGNE-101-2.

APPLICATION FOR UNITED STATES LETTERS PATENT  
DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**NUCLEIC ACID SEQUENCES ENCODING A PLANT CYTOPLASMIC PROTEIN  
INVOLVED IN FATTY ACYL-COA METABOLISM**

and which application was filed in the United States Patent and Trademark Office on May 30, 1996 having Attorney Docket No. CGNE 101-2, and the Serial Number designation 08/657,749, which application is a continuation-in-part of foreign application No. PCT/US94/13686 filed on 30 November 1994, which application is a continuation-in-part of US Serial No. 08/265,047 filed on June 23, 1994, which application is a continuation-in-part of US Serial No. 08/160,602 filed on November 30, 1993, which application is a continuation-in-part of US Serial No. 08/066,299 filed on May 20, 1993, which application is a continuation-in-part of Foreign application No. PCT/US92/09863 filed November 13, 1992, which application is a continuation-in-part of US Serial No. 07/933,411 filed August 21, 1992, which application is a continuation-in-part of US Serial No. 07/796,256 filed November 20, 1991.

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, and including any amendments filed concurrently with the application papers.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim benefit under the Paris Convention and 35 USC 119 of the priority of the following previously filed application(s):

<u>Country</u>	<u>Serial Number</u>	<u>Filing Date</u>
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No application to the invention of the present application was filed in any foreign country prior to the above application(s).

I hereby claim the benefit under Title 35, United States Code, 120 of each United States application listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, 112, I acknowledge the duty to disclose material information as defined in the Title 37, Code of Federal Regulations, 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

Prior U.S. Application(s)

<u>Serial No.</u>	<u>Filing Date</u>
08/265,047	6/23/94
08/160,602	11/30/93
08/066,299	5/20/93
07/933,411	8/21/92
07/796,256	11/20/91

I hereby appoint

Donna E. Scherer, Reg. No. 34,719  
Carl J. Schwedler, Reg. No. 36,924

my attorney of record/agent with full power of substitution and recovation to prosecute this application and to transact all business in the Patent Office.

All further correspondence should be addressed to:

Calgene, Inc.  
1920 Fifth Street  
Davis, CA 95616  
Telephone: (916) 753-6313

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: James George Metz

Inventor's Signature: James George Metz Date 9/10/96  
Residence and Post: 2803 Belhaven Place  
Office Address Davis, CA 95626  
Citizenship: USA

Full Name of Inventor: Kathryn Dennis Lardizabal

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Inventor's Signature: Kathryn Dennis Lardizabal Date 9/10/96  
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Citizenship: USA

Full Name of Inventor: Michael W. Lassner

Inventor's Signature: Michael W. Lassner Date 9/10/96  
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Citizenship: USA



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

James G. METZ *et al.*

Appl. No.: 08/657,749

Filed: May 30, 1996

Title: **Nucleic Acid Sequences Encoding  
a Plant Cytoplasmic Protein  
Involved in Fatty Acyl-CoA  
Metabolism**

Art Unit: 1638

Examiner: Russell KALLIS

Atty. Docket: 16518.025

**Amendment and Response to Office Action mailed November 19, 2003**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

***Attn: Mail Stop AF***

Sir:

In response to the Office Action mailed November 19, 2003, Applicants submit the following amendments and remarks.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, authorization to charge such fees is given in the accompanying transmittal letter.

***Amendments to the Specification***

This application is a ~~continuation~~ **continuation-in-part** of PCT/US94/13686, filed November 30, 1994, which is a ~~continuation-in-part~~ of USSN 07/796,256, filed November 20, 1991, a ~~continuation-in-part~~ of USSN 07/933,411, filed August 21, 1992, a ~~continuation-in-part~~ of PCT/US92/09863, filed November 13, 1992, a ~~continuation-in-part~~ of USSN 08/066,299, filed May 20, 1993, and a ~~continuation-in-part~~ of 08/160,602, filed November 30, 1993, and a continuation-in-part of ~~ef~~ USSN **U.S. Patent Application Serial No. 08/265,047, filed June 23, 1994, now issued U.S. Patent No. 5,679,881.**



***Amendments to the Claims***

1. (Previously Presented) A method for the production of an increased level of very long chain fatty acid molecules in a plant seed cell, said method comprising the steps of:  
  
growing a plant under conditions wherein said plant produces long chain fatty acyl-CoA molecules in said plant seed cell,  
  
in the presence of an expression product of a jojoba  $\beta$ -ketoacyl-CoA synthase DNA sequence operably linked to regulatory elements for directing the expression of said DNA sequence such as to effect the contact between such long chain fatty acyl-CoA molecules and said expression product,  
  
and producing said very long chain fatty acid molecules in said plant seed cell at a level that is increased relative to the native level of said very long chain fatty acid molecules in said plant seed cell.
2. (Previously Presented) The method of Claim 1 wherein said very long chain fatty acid molecules are produced in said plant seed cell to a level greater than 7% by weight.
3. (Original) The method of Claim 1 wherein said regulatory elements direct preferential expression of said DNA sequence in plant seed embryo cells.

4 – 10 (Cancelled)

11. (Original) The method of Claim 1 wherein said regulatory elements direct preferential expression of said DNA sequence in plant seed embryo cells.
12. (Previously Presented) A plant seed containing very long chain fatty acid molecules produced in accordance with Claim 1.
13. (Original) A plant seed produced in accordance with Claim 1.
- 14 – 28 (Cancelled)
29. (Previously Presented) A method for altering the composition of fatty acids in a plant cell, said method comprising the steps of:
  - growing a plant under conditions wherein said plant produces long chain fatty acyl-CoA molecules,
  - in the presence of an expression product of a jojoba  $\beta$ -ketoacyl-CoA synthase DNA sequence operably linked to regulatory elements for directing the expression of said DNA sequence such as to effect the contact between such long chain fatty acyl-CoA molecules and said jojoba  $\beta$ -ketoacyl-CoA synthase, wherein
    - (i) said jojoba  $\beta$ -ketoacyl-CoA synthase is capable of catalyzing the production of very long chain fatty acids from a long chain fatty acyl-CoA substrate and malonyl-CoA,
    - (ii) said DNA sequence is heterologous to said plant, and
    - (iii) very long chain fatty acids are produced in said plant such as to alter the overall fatty acid composition of said plant cell.

30. (Previously Presented) The method of Claim 1, wherein said very long chain fatty acid molecules are produced in said plant seed cell to a level greater than 5% by weight.
31. (Previously Presented) The method of Claim 1, wherein said very long chain fatty acid molecules are 24:1 very long chain fatty acid molecules.
32. (Previously Presented) The method of Claim 1, wherein said very long chain fatty acid molecules are 22:1 very long chain fatty acid molecules.
33. (Previously Presented) The method of Claim 1, wherein said very long chain fatty acid molecules are 20:1 very long chain fatty acid molecules.
34. (New) The method of Claim 29, wherein said plant cell is a plant seed cell.
35. (New) The method of Claim 34, wherein said very long chain fatty acids are produced in said plant seed cell to a level greater than 7% by weight.
36. (New) The method of Claim 34, wherein said very long chain fatty acids are produced in said plant seed cell to a level greater than 5% by weight.
37. (New) The method of Claim 29, wherein said very long chain fatty acids are 24:1 very long chain fatty acids.
38. (New) The method of Claim 29, wherein said very long chain fatty acids are 22:1 very long chain fatty acids.

39. (New) The method of Claim 29, wherein said very long chain fatty acids are 20:1 very long chain fatty acids.

## Remarks

None of the pending claims have been amended in this Response. New claims 34-39 have been added. No new matter has been added by these amendments. Support for these amendments may be found in the sequence listing, in the original claims, the figures, and throughout the specification. *See, e.g.*, specification at page 2, lines 11-21; page 13, lines 6-15; page 19, line 6 through page 21, line 31; page 74, lines 1-12; Tables 3-7; Example 8; and Examples 10 - 12. Additional description of the support for new claims 34-39 is provided below. This application presently contains claims 1-3, 11-13, and 29-39.

In order to facilitate prosecution, and without acquiescing to the Examiner's characterizations of references or the Examiner's characterizations of the instant claims, the priority claim has been amended. No new matter enters by these amendments. Support for these amendments can be found in the transmittal letter filed with the application on May 30, 1996, and in the declarations. Applicants bring to the Examiner's attention that a Request for Corrected Filing Receipt has been filed concurrently with this Response, in order to update the priority information.

### *I. Support for New Claims*

Applicants thank the Examiner for indicating that claims 1-3, 11-13, and 29-33 are deemed free of the prior art (Final Action at page 3), and for withdrawing the rejections of claims 1-6, 11-13, and 29 under 35 U.S.C. § 112, first paragraph, in view of Applicants' Amendments. Final Action at page 2.

Applicants also thank the Examiner for indicating during a December 9, 2003 telephone conference a willingness to consider – pending approval from a supervisory examiner – new dependent claims based on independent claim 29. To this end, new claims 34-39 have been added. As discussed in the December 9 conference, claims 1 and 29 are method claims directed to “[a] method for the production of an increased level of very long chain fatty acid molecules in a plant seed cell,” and “[a] method for altering the

composition of fatty acids in a plant cell,” respectively. Moreover, as discussed during the December 9 conference, new claims 34-39 adopt language used in previously presented claims 2 and 30-33, which are among those claims previously deemed free of the prior art. Final Action at page 3.

Applicants reiterate that no new matter has been added by the incorporation of new claims 34-39. Applicants submit that support for claim 29 may be found, for example, in the specification at page 74, lines 1-12<sup>1</sup>; in Tables 3-7 (and in text accompanying said Tables); and in Examples 8-12. Support for new claim 34 may be found, for example, in the specification at page 2, lines 11-18; at page 12, lines 12-15; in Example 11; and in Tables 3-7 (and accompanying text). Support for new claims 35-39 may be found, for example, in the specification at page 74, lines 1-12<sup>2</sup>; at page 83, lines 21-27; and in Tables 3-7 (and accompanying text).

## **II. *Objection to the Priority Claim***

The Office maintains its objection to the priority claim on the following grounds.

Applicant's asserts priority to USSN 08/066299 that issued as U.S. Patent 5,445,947 because the application USSN 08/066299 allegedly describes the jojoba  $\beta$ -ketoacyl-CoA synthase cDNA sequences of the instant application. However, the identity and function of the jojoba clones described in figures 2 and 3 of USSN 08/066299 were not known. Further, there is no support in the USSN 08/066299 application for the methods of the instant claims, namely methods of increasing or altering very long chain fatty acid molecules using a cDNA encoding a jojoba  $\beta$ -ketoacyl-CoA synthase. The instant application is drawn to a polynucleotide encoding a polypeptide having a  $\beta$ -ketoacyl-CoA synthase activity, which was first

<sup>1</sup> Stating, for example, that “[i]n plants that do accumulate VLCFA, pCGN7626 shifts the fatty acid composition towards longer VLCFA.” *See, e.g.*, specification at page 74, lines 10-12.

<sup>2</sup> Stating, for example, that “[a]nalysis of T3 seed oil from LEAR plants transformed with the jojoba CE shows that up to 7.8% of the seed oil is 24:1.” *See, e.g.*, specification at page 74, lines 1-3.

disclosed in parent application 08/265,047 filed 06/23/1994  
now issued U.S. Patent 5,679,881. Accordingly, the  
effective filing date of the instantly claimed invention is 23  
June 1994.

Final Action at page 2. In order to facilitate prosecution, and without acquiescing to the Examiner's characterizations of the above-referenced documents, or the Examiner's characterizations of the instant claims, Applicants have amended the priority claim. In light of these remarks, Applicants therefore respectfully request withdrawal of this objection.

### ***III. Objection to the Specification – Sequence Rules***

In the Office Action mailed March 11, 2003, the Office requested that Applicants amend the application to comply with the requirements of 37 C.F.R. § 1.821-1.825. Office Action at page 2. Applicants note that in the Final Office Action mailed November 19, 2003, the Examiner has not addressed Applicants' amendments to the sequence listing and the specification in order to comply with 37 C.F.R. § 1.821-1.825. These amendments were submitted as part of Applicants' Response to the Office Action mailed March 11, 2003 (which Response was filed on August 11, 2003), and Applicants' corrected submission filed September 29, 2003. Applicants respectfully request clarification of the status of this objection.

### ***IV. Double Patenting Rejection***

Claims 1-3, 11-13 and 29-33 stand rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 5,679,881. Without acknowledging the appropriateness of this rejection, and without acquiescing to the Examiner's characterizations of the instant claims or of claims 2-3 of U.S. Patent No. 5,679,881, Applicants include herewith a Terminal Disclaimer over U.S. Patent No. 5,679,881. Applicants therefore submit that the grounds for the

double patenting rejection have been rendered moot, and respectfully request withdrawal of this rejection.



**Conclusion**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5512 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in cursive script that reads "Rachel L. Adams".

David R. Marsh (Reg. Attorney No. 41,408)  
Rachel L. Adams (Reg. Attorney No. 54,660)  
Holly Logue Prutz (Reg. Attorney No. 47,755)

Date: December 16, 2003

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